IBC Reviewer

User Guide

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1 Introduction

eProtocol is a Key Solutions Protocol Management System (PMS) tool used to manage the submission, review and approval process for protocols used in a variety of research projects. The software helps eliminate application errors, and improves collaboration and communication among research teams. This document focuses on the role of the Reviewer in the overall process.

This document explains the functions of the reviewer. Using the eProtocol application, the reviewer can review a protocol and give his feedback on a protocol to the PI or to the Manager (e.g., recommending the protocols for approval, sending comments to the Investigator about a protocol). Also the reviewer can search for a protocol.

Separate eProtocol guides are available to personnel assigned to the roles of Principle Investigator, Manager, Site Administrator, Company Administrator, and Committee Manager.

1.1 General Information

This is the Note icon. It indicates information requiring special attention.

This is the Warning icon. It indicates a problem that must be avoided.

Table 1 - Common Acronyms and Definitions Encountered in this Guide

Acronym	Stands For	Definition
PI	Principal Investigator	The person responsible for creating, completing, and submitting a protocol.
Protocol ID	Protocol Identification Number	A unique ID assigned to a protocol when it is created. This is used mainly for identification purpose, and it stays with the protocol throughout its lifecycle.
IBC	Institutional Biosafety Committee	Committee of persons responsible for the ethical review of protocols submitted by a principal investigator (PI) within a research organization where biological materials are research subjects.
Manager	Manager	The person responsible for coordinating the review process (assigning reviewers, reviewing and forwarding comments to PIs, reviewing and returning responses to Reviewers from the PI, generating

		meeting agendas and meeting minutes, and approving protocols).
PR	Primary Reviewer	The primary person requested to review a protocol submitted to the IBC. Comments cannot be forwarded to the PI for response until all the Primary Reviewers assigned for that protocol have provided their comments.
PDF	Portable Document Format	An Adobe Acrobat file type utilized for attachments.
SR	Secondary Reviewer	A committee member assigned a protocol for review, but others comments can be forwarded to the PI without receiving comments from the Secondary Reviewer(s).

Table 2 - Color Coding Definitions

Color	Definition
Light Brown	The protocol is assigned for a Full Committee Review.
Pink	The protocol is assigned for Designated Review process; the reviewers are yet to give their feedback.
Yellow	Only the Role column for a protocol is highlighted yellow when the reviewer is: • Asked by the Manager for their decision on whether a Full Committee Review is required. • Assigned as Primary or Secondary Reviewer by the Panel Manger.
Peach Pink	Only the Role column for a protocol is highlighted Peach Pink (or Orange) when the reviewer is assigned as Presenter by the Panel Manger.
Blue	Only the Role column for a protocol is highlighted blue when the reviewer is assigned as Non-Primary Reviewer by the Manager.

Do not use the Back or Next buttons on your browser while using eProtocol, as this will result in you being logged out of the system. Instead, use the menu items found in the eProtocol module that you are working on.

i The chevron symbol to the far right of the category headings on the homepage is used to expand or collapse the category of protocol application that you are working on.

i Use the bread crumb links in the upper left-hand corner of each section to move up through the hierarchy of the eProtocol system. The links are so named because they show you exactly where you are and how to get back to where you were before.

1.2 Logging Into eProtocol

i If your institution uses Single Sign-on (SSO) this section does not apply.

Before you begin, contact **the Company Administrator** to obtain the proper login credentials. Once you have your login credentials, go to your computer and open your browser (e.g., Firefox). It is important to deactivate the pop-up blocker for the smooth operation of eProtocol. Once you have finished those tasks, do the following:

1. Open the Key Solutions eProtocol web page (eprotocol-inst.keyusa.net).
2. Enter your login and password in the spaces provided on the far right of the page, as shown in Figure 1: eProtocol Login. This is your regular login.

User ID
Password

Login   Forgot Password

Figure 1: eProtocol Login

3. Click **OK**.

i If you forget your password, you can request a new one via the regular process. Once the password is reset, the Change Password window will pop up prompting you to enter a new password upon logging in.

If the User ID and/or Password are incorrect, the message 'Login Failed Invalid User ID or Password' is displayed.

2 Reviewer Homepage

Within eProtocol, a Reviewer is responsible for reviewing assigned protocols and providing feedback to the PI or the Manager regarding those protocols. Feedback includes decisions on the need for full board review of a protocol and through participation in protocol review process, making a recommendation on the approval of the protocol.

When you login to the system as a Reviewer the first page you are shown is the Reviewer Homepage. The Reviewer Homepage displays the various functions in an easy access format, allowing you one-click access to each function. Though similar, the Reviewer functionalities are different for the various eProtocol modules (IBC, IRB and IBC).

You can navigate to the Homepage at any time by pointing to **eProtocol**>**Reviewer** in the top left corner of the screen and clicking **Reviewer** or **Reviewer Home** on the sub-menu as shown Figure 2: .

Figure 2: Reviewer Submenu

Your name and your location (Lakeview) appear in the upper right-hand corner of the Homepage, as shown in Figure 3: Reviewer Name and Institution/ Location.

Figure 3: Reviewer Name and Institution/ Location

Figure 4: Reviewer Homepage

> Please Note that whenever you want to view the protocol details click Protocol ID link.

> To sort the protocols in ascending/descending order in a column, click the Column Header.

> Please Note you can use the Show/Hide icons (up/down chevrons on the right side of the grey section headers) to view/hide the protocols lists.

The committees to which you are assigned appear on the dashboard as committee tabs. Select the **Committee** tab to view the protocols for that committee.

Reviewer dashboards have two sections:

1. IBC Member (Action Items) - The protocols which are assigned to the Reviewer for review decision or for approval.

2. IBC Member (Protocols for Review) - The protocols the reviewer has already seen and provided feedback which may require additional attention once the PI or Manager has taken action.

Each Section has the following form types sub sections:

i Please Note the form types are based on the selected committee (e.g., IBC –New, Amendment, Continuing Review, and Closure Report).

The different form types shown on the Reviewer dashboard are explained in Table 3.

Table 3 – Protocol Form Types on Reviewer dashboard

Form Types	Explanation
New	The protocols that are newly created are displayed.
Amendment	The revision forms for approved protocols to submit the revisions made after protocol approval are displayed.
Continuing Review	The forms for continuing or annual review of approved protocols which are approved for multiple years but need intermediate reviews on an annual basis.
Closure Report	The final report forms created for closing approved protocols for which the research is concluded.

Each form type section has following columns:

Table 4 – Columns in Form Type section and their Definitions

Column	Definition
Role	Reviewer Role assigned to Panel Members by Manager (e.g., Presenter, PR,SR, NPR)
Protocol ID/	A unique ID assigned to a protocol when it is created for identification purpose, and it stays with the protocol throughout its lifecycle - all the way to the archival.
Principal Investigator	Name of the Principal Investigator for the eProtocol.

Protocol Event	The current status of the eProtocol: • **Assigned as Reviewer**: You have been assigned as a reviewer for the protocol, and you have not yet started the review or started the review but did not send approval decision or comments to the Manager. • **Recommended for Approval**: You have recommended the protocol for approval. • **Comments Sent**: You have submitted comments for the protocol. For First Comment: Comment Sent (Cycle 1), For Second Comment: Comment Sent (Cycle 2), so on... • **Responses Received**: The Manager has forwarded the responses of Investigators to the comments submitted. For First Response: Responses Received (Cycle 1), For Second Response: Responses Received (Cycle 2), so on... • **Moved**: The protocol is moved to some other meeting date from the assigned meeting date. In this state, you can continue the review process. • **Tabled**: The protocol is not completely discussed due to some unresolved issues during the meeting and tabled for discussion in another meeting. When a protocol is tabled, the review process should be re-initiated by the committee for further processing. In this state, you can continue the review process. • **Contingent**: Protocol is approved on contingent criteria. Contingent Approval is also known as Conditional Approval. In contingent status, the Manager can directly communicate with Investigator without your comments. However, you can continue the review process.
Panel	The name of the panel to which the protocol is assigned.
Meeting Date	The date of meeting on which the protocol is scheduled for review.

2.1 Reviewer Functions

You have to review the protocol and give your views/feedback on the protocol to the PI or to the Manager. There are three types of feedback:

1. A Decision on the protocol (Full Review or Designated review)
2. Comments on the protocol for the PI

3. A recommendation on the protocol

Sending comments for the PI for response (either the answer to a question or a change to the protocol) is the first step of a Comment/Response cycle. Once comments are sent to the PI (via the Manager) the PI must respond; the responses (including any changes to the protocol are returned (via the Manager) to all the reviewers to complete the Comment/Response cycle. The review process may consist of zero or more review cycles – zero cycles if the protocol is recommended for approval as is (there are no comments); one or more cycle depending on the changes required.

2.1.1 Making a Decision on the Protocol for Further Review Process

If the Manager/Committee Manager requests your opinion on whether the protocol should undergo a **Full Review** or a **Designated Review**, you have to review the protocol and give your decision to the Manager.

> Navigate to the homepage at any time by pointing to the **eProtocol>Reviewer or Reviewer Home** in the top left corner of the screen and clicking Reviewer as shown in Figure 5.

The protocols which are assigned to the Reviewer have a **light pink** background.

The **Role** column has **yellow color** background if a protocol is assigned to the Reviewer by the **Manager** for a reviewer decision (Full review or designated review) and **Assigned as Reviewer** appears in the **Protocol Event** column.

IBC Member (Action Items)						
NEW						
Role	Protocol ID	Principal Investigator	Protocol Event	Status/Comments	Panel	Meeting Date
Reviewer	IBC-16-12-041	Scott, Goodwin	Assigned as Reviewer	IN-PROGRESS	IBC Panel	
Presenter	IBC-16-12-037	Krall, Bonita	Assigned as Reviewer	IN-PROGRESS	IBC Panel	
Reviewer	16-12-012	Krall, Bonita	Assigned as Reviewer	IN-PROGRESS	IBC Panel	

Figure 5: Reviewers Assigned

Follow the steps to give your decision regarding the protocol:

1. Click **Assigned as Reviewer** link in the **Protocol Event** column of the **Role** with yellow background and light pink color in the row to open the **Comments** page (Figure 6) where you can give your decision on the protocol.

Figure 6: Review Decision on comment page

2. You can view the protocol by clicking the **Get Protocol** button on the right side of the page or by clicking the **Protocol ID link** on the left side of the page.

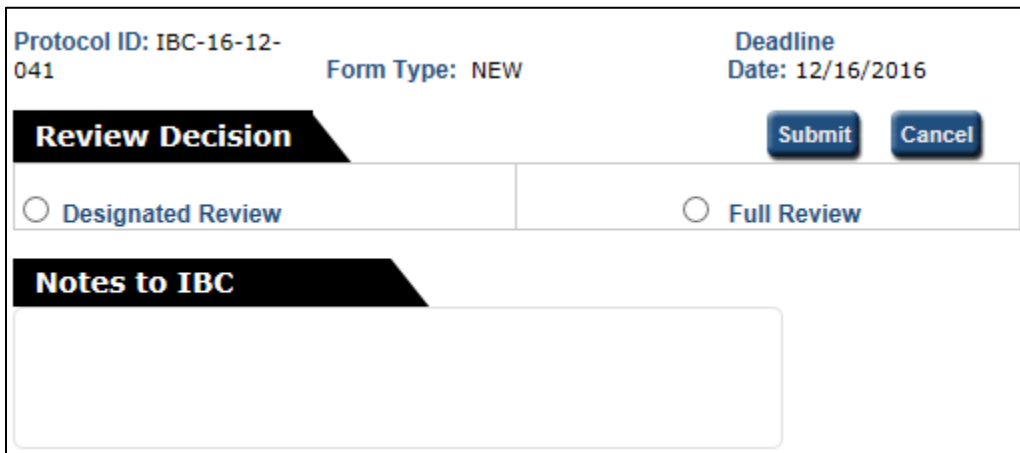3. Click the **Review Decision** button. This opens the **Review Decision** dialogue box (Figure 7)**.**

Figure 7: Review Decision dialogue box

 Please note whenever you want to close a dialogue box, you can click **Cancel** or the red X on the top right corner the box.

4. Click the desired **Review Decision** radio button - **Designated Review** or **Full Review**.

5. Enter the remarks in the **Notes to IBC** text field and click **Submit**.

This directs you to the **Homepage** and the protocol disappears from your homepage. However, the protocol reappears on your **Homepage** if you are assigned as a **Reviewer** by the **Manager**.

2.1.2 Sending Comments to the PI

While reviewing the protocol, if you feel any section/ information/ aspect/ answer is incomplete, needs improvement, or if you need some more information, you can write and submit comments

to the Manager. The Manager is responsible for reviewing and consolidating the comments prior to submitting them to the PI.

> ⓘ Navigate to the homepage at any time by pointing to the **eProtocol>Reviewer or Reviewer Home** in the top left corner of the screen and clicking Reviewer as shown in Figure 5.

Do the following to write comments:

1. Click **Assigned as Reviewer** link in the **Protocol Event** column to open the **Comments** page.
2. Click **Write Comment(s)** button to bring up the **Comment** section shown in Figure 8.
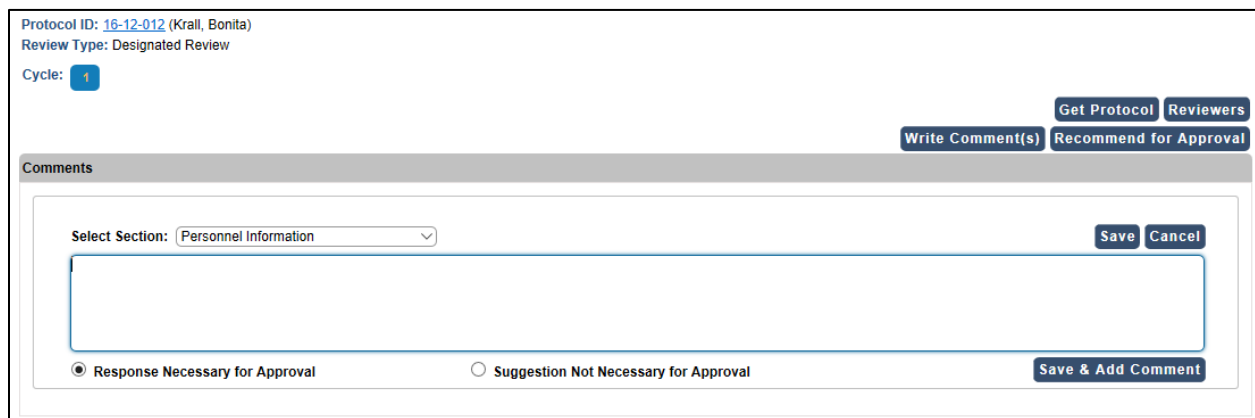
Figure 8: Writing Comments

3. Select the section on which you want to comment from the **Select Section** drop down list. The sections in dropdown list are the protocol form (e.g., Personnel Information, Project Registration, Protocol Summary, Research Location, etc.).
4. Enter the comments in the text field provided.
5. Click the appropriate radio options- **Response Necessary for Approval** or **Suggestion Not Necessary for Approval**.

   a. Select the **Response Necessary for Approval** - if the Investigator's response to the comment is mandatory.
   b. Select **Suggestion Not Necessary for Approval** - if the Investigator's response to the comment is optional.

6. Click **Save**. This saves the comments and the **Submit to IBC** button appears shown in Figure 9.

> ⓘ If you select the **Suggestion Not Necessary for Approval** for all the comments, the **Submit to IBC** button is disabled.

i If you select the **Response Necessary for Approval** for any comment, the **Recommend for Approval** button is disappears. And you can Recommend for Approval in next cycle.
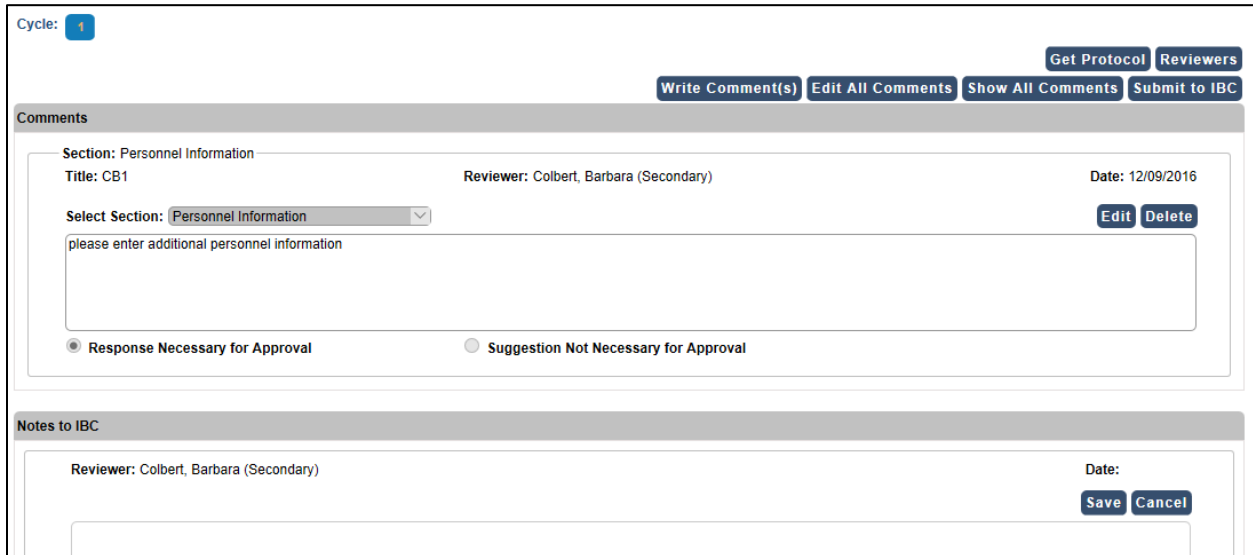
Figure 9: Comments Saved

    a. You can add more comments by clicking the **Save & Add Comment** button (Figure 8) or the **Write Comment(s)** button (Figure 9).

    b. You can view and edit more than one comment by clicking the **Edit All Comments** button. This opens the **Edit All Comments** dialogue box. Make the required changes and click **Save**. This directs you to the **Comments** page showing all the modifications.

i On the Comments page you can:
- View all comments/responses by clicking the **Show All Comments** button.
- View the Comments and Responses of any cycle by clicking the **Cycle Number** icon on left side of the page.
- View the form related guidelines by clicking the **Guidelines** button.
- Delete the comments by clicking the **Delete** button.
- Modify the comments by clicking the **Edit** button.

i You cannot edit or delete the comments from a previous cycle.

i When you send the comments, an email is sent to the Manager with all details.

When you get a response from the Investigator, you will receive an email with all the details.

7. Enter remarks intended only for the IBC office in the **Notes to IBC** text field and click **Save**.

8. Click the **Submit to IBC** button

? Are you sure you want to submit all your comments and notes to IBC?

OK   Cancel
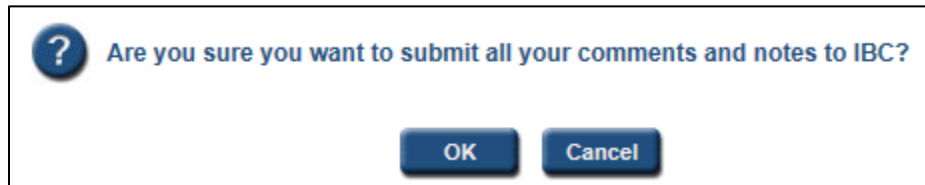
Figure 10: Confirmation dialogue box

9. Click **Ok** in the confirmation dialog box that appears; your comments and notes are sent to the Manager.

Now the protocol appears in **IBC Member Protocols for Review** section of your homepage as shown in Figure 11 and the **Protocol Event** changes to **Comments Sent**.

Role	Protocol ID	Principal Investigator	Protocol Event	Status/Comments	Panel	Meeting Date
Reviewer	16-12-012	Krall, Bonita	Comments Sent (Cycle 1)	IN-PROGRESS	IBC Panel	
Reviewer	16-12-009	Scott, Goodwin	Recommended for Approval	IN-PROGRESS	IBC Panel	01/02/2017

Figure 11: Protocol Event as Comments Sent (Cycle 1)

2.1.3 Reviewing Responses from the PI

When you receive a Comment Response from the Investigator, the protocol event changes to **Responses Received (cycle #)**.

1. Click **Responses Received (Cycle #)** link in the **Protocol Event** column on your **homepage**. This opens **Comments** page, where you can view responses to comments and any protocol updates, and make your recommendation or make additional comments.

2. Repeat the steps 3 to 10 in section 2.1.2 Sending Comments to the PI, to send new comments.

If you are satisfied by the responses given by the PI and want to recommend the protocol for approval, follow the instructions in the next section, 2.1.4 Recommending the Protocol for Approval.

2.1.4 Recommending the Protocol for Approval

i Navigate to the homepage at any time by pointing to the **eProtocol>Reviewer or Reviewer Home** in the top left corner of the screen and clicking Reviewer.

Role	Protocol ID	Principal Investigator	Protocol Event	Status/Comments	Panel	Meeting Date
Reviewer	16-12-012	Krall, Bonita	Responses Received (Cycle 1)	IN-PROGRESS	IBC Panel	
Presenter	IBC-16-12-037	Krall, Bonita	Assigned as Reviewer	IN-PROGRESS	IBC Panel	

IBC Member (Action Items) — NEW

Figure 12: Responses Received (Cycle1)

After reviewing the protocol, you can recommend the protocol for approval, if appropriate, by doing the following:

1. Click **Assigned as Reviewer** or **Responses Received (Cycle#)** link in the **Protocol Event** column; this opens the **Comments** page.

eProtocol » Reviewer » **Home** » Comments

Protocol ID: IBC-16-12-037 (Krall, Bonita)
Review Type: Designated Review
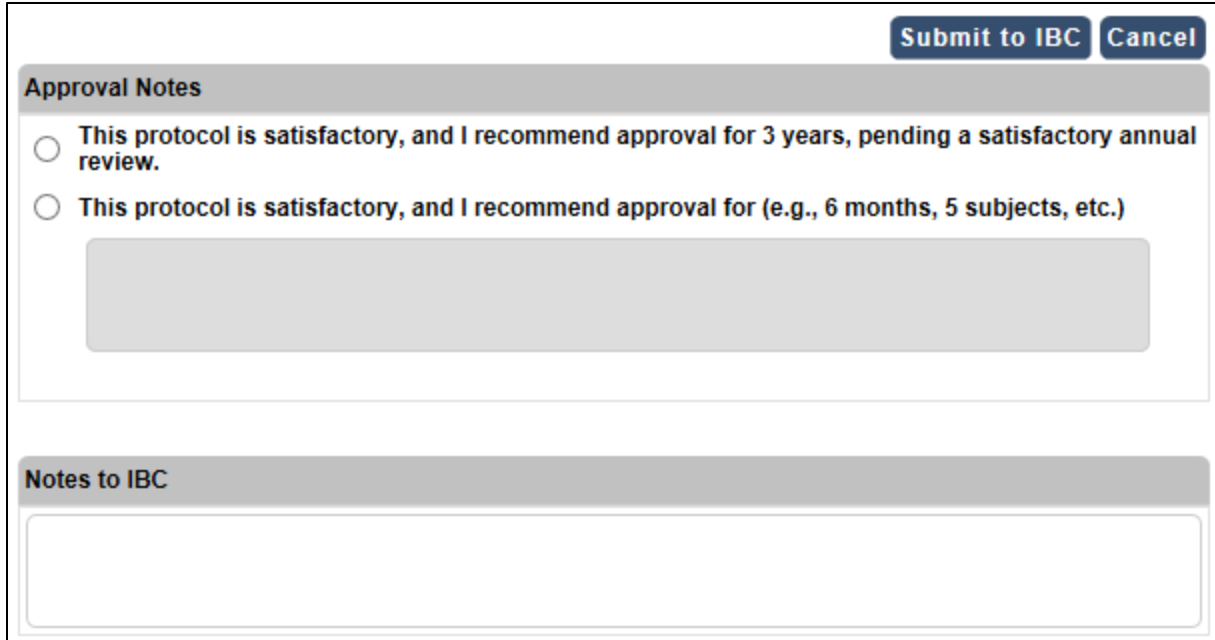
Get Protocol   Reviewers
Write Comment(s)   Recommend for Approval

Comments

Please click on Write Comment(s) to add Comment(s).

Figure 13: Reviewer Comments Page

2. Click the **Recommend for Approval** button. This opens the **Recommendation Notes** dialogue box, as shown in Figure 14: Approval Notes dialogue box.

Figure 14: Approval Notes dialogue box.

3. Select the appropriate radio option – **"The proposed is satisfactory…"** You can also enter notes in the text box below it which might be shared with other reviewer.

> *i* The Approval statement shown may differ from your system based on configuration.

4. Enter remarks in the **Notes to IBC**.
5. Click the **Submit to IBC** button. You are directed to the homepage where the protocol jumps to **Protocol for Review** from the **Actions Items** section to the **Protocols for Review** section as shown in Figure 15 and the protocol event changes to **Recommended for Approval**.

Figure 15: The Protocol Event as Recommended for Approval

> *i* After reviewing the protocol, if you have any additional comments on the protocol, you can write comments and submit them to the Manager. The Manager reviews the comments and sends them to the PI for response.

2.1.5 Searching for a Protocol

You can search for a specific protocol or a set of protocols that meet criteria you select, once you have found the desired protocol(s) you can open and review them by clicking the protocol ID link.

To search for a Protocol:

1. Point to the **eProtocol> Reviewer** on top left corner of the homepage and click on the **Search Protocol** sub menu (Figure 2) to open the **Search Protocol** page.

On this page, you will find several fields you can use in your search – you can use one (for example, Protocol ID or Study Tittle) or several (for example, Principle Investigator, Sponsor, and Protocol Status).

Depending on your organization the search fields may vary for what is shown here (Figure 16).

Figure 16: Search Protocol page

2. Enter/Select any of the details/fields and click **Search**, the matching protocol(s) appear below the search criteria as shown in Figure 17: Protocol .

Figure 17: Protocol Search Results

> *i* To sort the protocols in ascending/descending order in a column, click the Column Header.

> *i* You can use the Show/Hide icons (up/down chevrons on the right side of the grey section headers) to view/hide the protocol lists.

3. Click on the **Protocol ID** link to open the desired protocol.

> *i* Use Clear to clear the search criteria entered and start new search.

4. If you want to save the Search Criteria to re-use in the future;
   a. Click **Save** on search protocol page. This displays **Search Criteria** text field, plus the **Save**, and **Cancel** buttons, as shown in Figure 18.

Figure 18: Search Criteria textbox

   b. Enter the name you want to use in the future to refer to these search criteria in the **Search Criteria** text field and click **Save**. This saves the search criteria with the given name and adds the name to the **Selected Search Criteria** drop-down list, as shown in Figure 19.

Figure 19: Selected Search Criteria drop-down list

5. You can add other search criteria to the **Selected Search Criteria** drop down list, perform steps 2 thru 4.

To view the list of protocol searches, click the **Selected Search Criteria** from the drop-down.

3

4 Appendix A – Getting Started Tips

4.1 Disabling Pop-ups

To view pop-ups in the application, you must set browser to allow pop-ups for the application.

4.1.1 For Mozilla

A dialogue box appears once you login for first time, Click **Ok** to confirm.
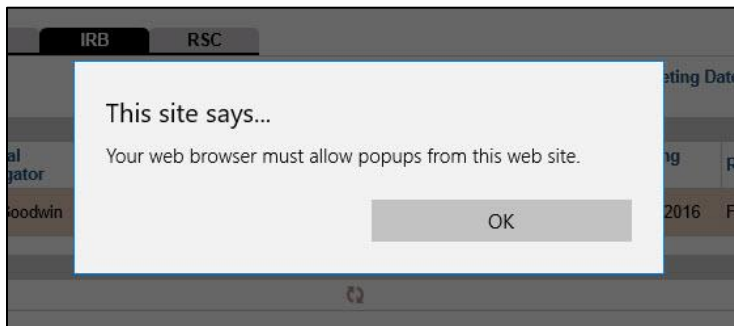
Figure 20: Allow pop-ups dialogue box

Click the right corner menu button on the screen and click Options as shown in.Figure 21.
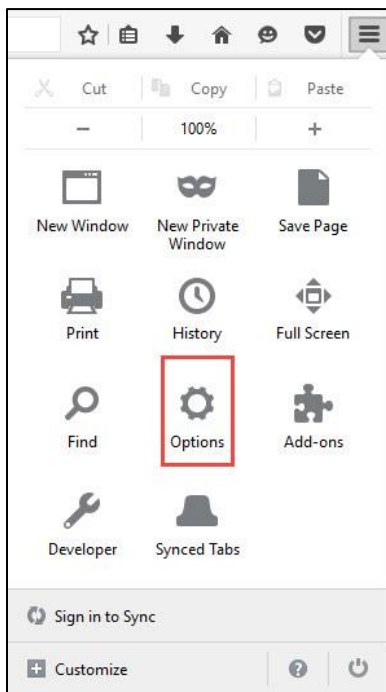
Figure 21: Choose options

Click **Content** on left navigation pane and check the **Pop-ups** check box as shown in Figure 22.
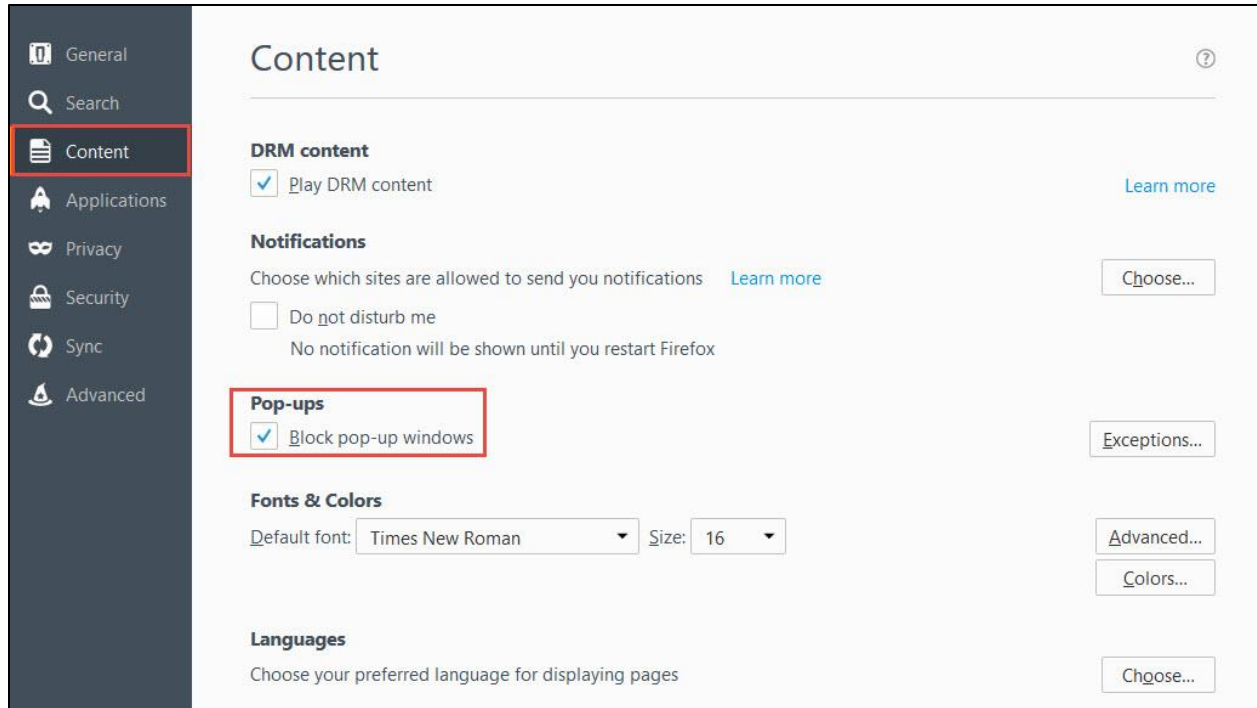
Figure 22: Pop-ups check box

4.1.2 For Internet Explorer

A dialogue box appears once you login for first time, Click **Ok** to confirm.
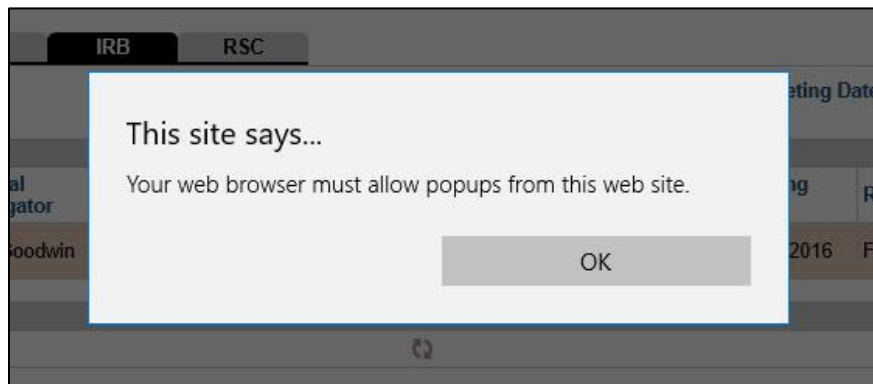
Figure 23: Allow pop-ups

A confirmation dialogue box appears on bottom of the page, Click **Allow Once** or **Always Allow** to confirm.
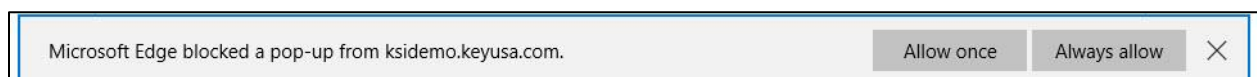
Figure 24: Confirmation box

4.1.3 For Chrome

A dialogue box appears once you login for first time, Click **Ok** to confirm.
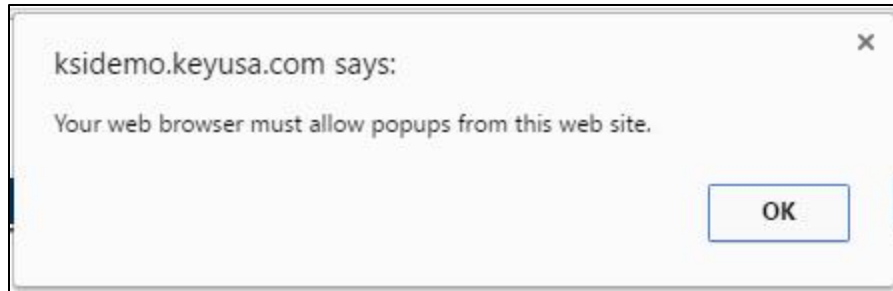
Figure 25: Allow pop-ups

A pop-ups blocker icon appears on the right corner of the URL field. Click on icon and select the **Allow pop-ups** radio option and click **Done**.
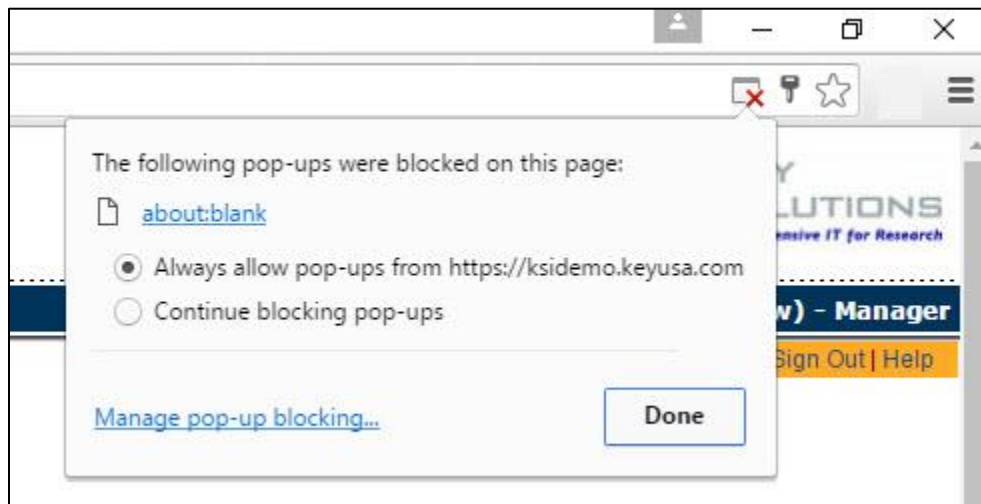
Figure 26: Pop-up dialogue box

Do not use the back button of the browser while using the **eProtocol** application. Instead, use the navigation links at the top of the screen. This will lead you to the path that you have followed to navigate to where you are within **eProtocol**. You can click a link to go back to that page.
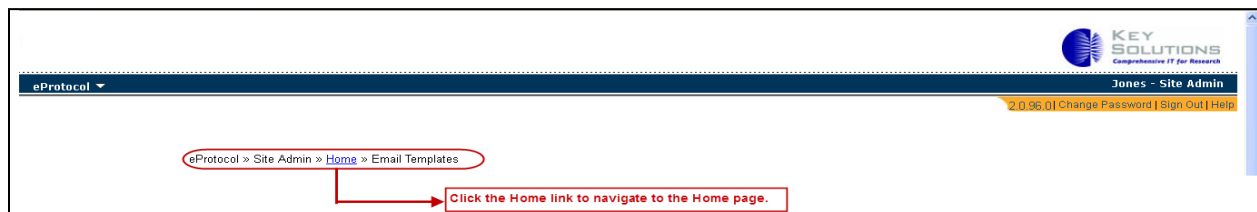
Figure 27: bread crumb

Do not close the application without signing off. Click the **Sign Out** link to sign off from the eProtocol application

Figure 28: Sign Out link

Click the **Help** link to get help content (if implemented) for the page you are currently on.
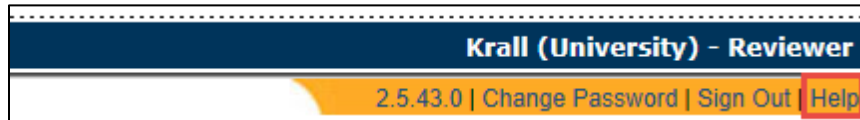
Figure 29: Help Link

4.2 Password Management Assistance
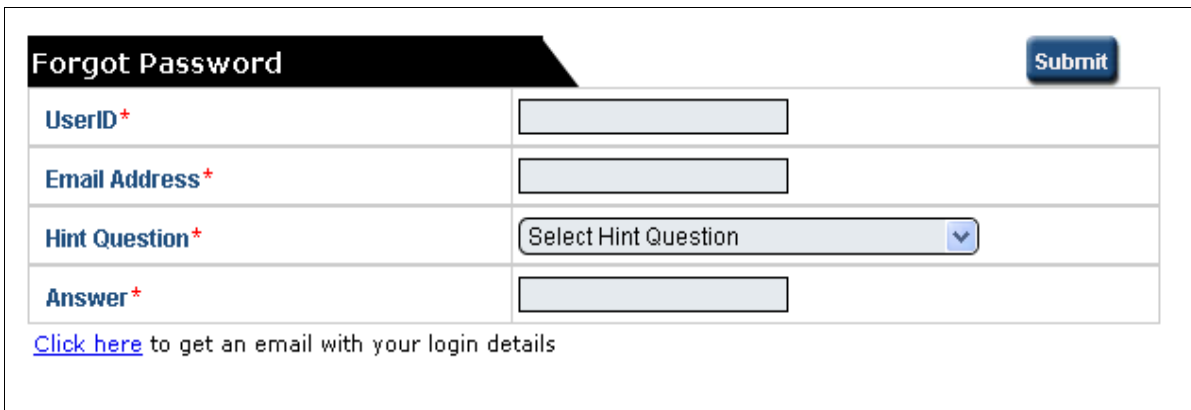
4.2.1 Forgot Password

If you do not remember the password, click the **Forgot Password** button on login page to retrieve the password.

Figure 30: Forgot Password Icon

Enter the required details in the respective fields, select the **Hint Question** from the drop-down list and enter the answer in the **Answer** field to retrieve the password.
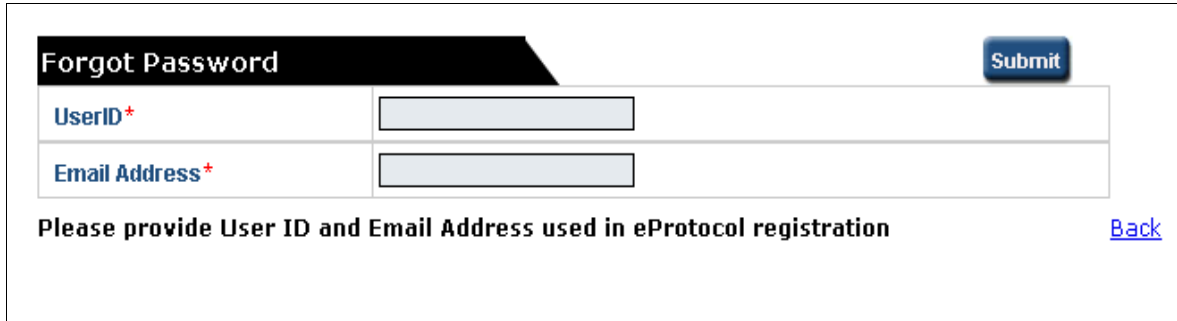
Figure 31: Forgot Password Fields

The **Click here** link helps the user to receive the login details to the registered email address.

Enter the **UserID** and **Email Address** in the respective fields and click **Submit** as seen in Figure 32.

Figure 32: Retrieve Password using Credentials

The registered user now receives the email with a URL to change password.

Figure 33: The email sent to a user

Click on the URL to open the **Reset Password** page.

1. Enter your **UserID** and **Email ID** (the email id on which you will receive a new password).
2. Select the **Hint Question** from the drop-down list and enter an answer for the question.
3. Click the **Submit** button. The details are submitted. An email with the new password is sent to the specified email id.

You can use this new password or change it by clicking the **Change Password** link on top right corner of the application.

> Password Strength has been enhanced by adding certain attributes the password must contain

- ✓ At least 8 characters
- ✓ At least two of the following:
- ✓ Uppercase Letters
- ✓ Lowercase Letters
- ✓ Numbers
- ✓ Symbols

Password strength will be displayed beside the **New Password** field, if the strength is good then the color changes to green color.

4.2.2 Change Password

In the existing system there is change password link in the upper right of the primary pages. Click it and a pop-up is displayed with the respective fields to help the user to the password as seen in Figure 35.

Figure 34: Change Password Link

The **Change Password** window pops up.
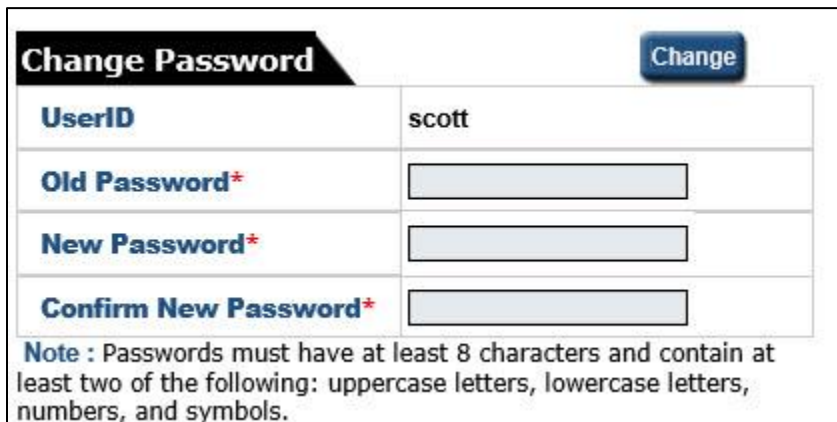
Figure 35: Change Password Fields

4. Enter the old password. Also, enter the new password and confirm it.
5. Click the **Change** button. The password is changed and you are directed to homepage.

The password must contain:
- At least 8 characters
- At least two of the following:
  - o Uppercase Letters
  - o Lowercase Letters
  - o Numbers
  - o Symbols

The password strength is displayed beside the New Password field, if the strength is acceptable then the color of the stars changes to **green**.

If you do not remember the old password, you can request a Company Administrator to initiate the changing of the password. Once a Company Administrator changes the password, you can login to the system with the password given by Company Administrator. The Change Password window pops up.

5 Appendix C - List of Figures